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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/777,736	02/12/2004	Corey A. Burchman		5616

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EXAMINER

HUH, BENJAMIN

ART UNIT PAPER NUMBER

3767

DATE MAILED: 07/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/777,736	Applicant(s) BURCHMAN, COREY A.	
	Examiner Benjamin Huh	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 2/12/04.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 2/12/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Specification

The disclosure is objected to because of the following informalities: Page 10 lines 2-3 state that the retaining rod to be element 420, it is believed that the applicant meant to state that the retaining rod is element 424 since element 420 is the inner body wall.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-2 & 4-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Rand (US Patent No. 4841970). The Rand reference discloses a device for cooling and thereby de-sensitizing an area, the device comprising a body 2 comprising an open end, an interior wall extending inwardly from the open end, the interior wall partially defining a reservoir that extends into the body; a cover 9 removably sealing and closing the open end of the body, the cover and interior wall enclosing the reservoir; a cooling medium 7

in the reservoir; and means for retaining 6 the cooling medium in the body when the cover is removed; the body, cover and cooling medium capable of being cooled to an application temperature substantially below room temperature; whereby removing the cover exposes the cooled cooling medium such that placing the open end of the body against the skin causes sufficient heat transfer between the cooling medium and the skin to materially de-sensitize the skin and wherein the device would be fully capable of de-sensitizing an area of human skin immediately prior to hypodermic injection due to it's size, shape, and ability to work in the environment.

With respect to claims 2 & 4-5, wherein the cooling medium 7 is solid at the application temperature and liquid at room temperature and can comprise water or a water mixture, see col. 3 lines 9-12.

With respect to claim 6, wherein the cover 9 is formed from substantially planar sheet material, see figures 1-3.

With respect to claim 7, wherein the body is a single piece of plastic, col. 1 lines 56-59, col. 2 lines 30-31, & figures 1-3.

With respect to claim 8, wherein the open end of the body has an elongated shape, see figures 1-3.

With respect to claim 9, wherein the body comprises an applicator portion at the open end of the body to be pressed against the skin and a handle portion defining a handle at the other end of the body, a substantially portion of the handle away from the cooling medium to enable grasping the handle without substantial heat transfer through the handle to the cooling medium, see figures 1-3.

With respect to claim 10, wherein the open end of the body is sized such that it is fully capable of simultaneously cooling a plurality of injection sites on the skin due to it's size, shape, and ability to work in the environment, see figures 1-3.

With respect to claim 11, wherein the cover 9 is a first cover and the cooling medium incorporates a second cover 8 closing the open end of the body, the second cover sealingly mounted on the body and remaining on the body after the first cover is removed, see figures 1-3.

With respect to claim 12, wherein the retaining means 6 comprises structure extending inwardly into the reservoir from the body wall and engaging the cooling medium, see figures 2-7 and col. 2 lines 51-60.

With respect to claim 13, wherein the open end of the body is sized such that the device is fully capable of cooling an area of skin away from the injection site and infiltrated by medicant due to it's size, shape, and ability to work in the environment.

Claims 1, 6, 8-10, & 13 are rejected under 35 U.S.C. 102(b) as being anticipated by McGee (US Patent No. 2825339). The McGee reference discloses in figure 1 a device for cooling and thereby de-sensitizing an area of human skin, the device comprising a body (10,11) comprising an open end, an interior wall extending inwardly from the open end, the interior wall partially defining a reservoir that extends into the body; a cover 36 removably sealing and closing the open end of the body, the cover and interior wall enclosing the reservoir; a cooling medium (see col. 2 lines 68-70) in the reservoir; and means for retaining 35 the cooling medium in the body when the cover is

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removed; the body, cover and cooling medium capable of being cooled to an application temperature substantially below room temperature; whereby removing the cover exposes the cooled cooling medium such that placing the open end of the body against the skin causes sufficient heat transfer between the cooling medium and the skin to materially de-sensitize the skin and wherein the device would be fully capable of de-sensitizing the skin immediately prior to hypodermic injection due to it's size, shape, and ability to work in the environment, also see col. 1 lines 15-18 and col. 2 line 23 – col. 3 line 29.

With respect to claim 6, wherein the cover 36 is formed from substantially planar sheet material, see figure 1.

With respect to claim 8, wherein the open end of the body has an elongated shape, see figure 1.

With respect to claim 9, wherein the body comprises an applicator portion seen as the end closer to 36 at the open end of the body to be pressed against the skin and a handle portion seen as then end closer to 33 with respect to element 18 defining a handle at the other end of the body, a substantially portion of the handle away from the cooling medium to enable grasping the handle without substantial heat transfer through the handle to the cooling medium.

With respect to claim 10, wherein the open end of the body is sized such that the device is capable of simultaneously cooling a plurality of injection sites on the skin, see figure 1.

With respect to claim 13, wherein the open end of the body is sized such that the device is fully capable of cooling an area of skin away from the injection site and infiltrated by medicant due to its size, shape, and ability to work in the environment.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rand (US Patent No. 4841970) or McGee (US Patent No. 2825339) as applied to claim 1. Now even though Rand does not explicitly disclose the cooling medium to be sterile and the cover to maintain the sterile environment prior to use it would be obvious to one of ordinary skill in the art at the time of the invention to utilize sterile materials and to maintain sterile procedures in a medical procedure in order to prevent infection and other medical complications.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hommann et al (US Patent No. 6936028B2). The Hommann reference discloses a method of reducing pain generated by hypodermic injections in human skin, the method comprising the steps of applying a cooling medium against an area of skin, the

perimeter of the area enclosing an injection site, the cooling medium capable of cooling the skin sufficiently to simultaneously de-sensitize the injection site; maintaining the cooling medium against the area of skin for a length of time sufficient to materially de-sensitize the entire area of skin; and serially administering a hypodermic injection at the injection site while the area of skin remains. Now even though Hommann does not explicitly disclose to perform a plurality of injections at a plurality of injection sites it would be obvious to one of ordinary skill in the art at the time of the invention to perform a plurality of injections on the de-sensitized area of the skin in order to provide an added effect or delivery at a faster rate.

Claims 15-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hommann et al (US Patent No. 6936028B2) as applied to claim 14 and further in view of Hecmati (US Patent No. 4469676). Now even though Hommann does not explicitly disclose the use of ice as the cooling medium attention is directed to Hecmati. The Hecmati reference teaches the use of ice to numb the skin before an injection, see col. 4 line 47 – col. 5 line 12. Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to utilize ice to de-sensitize the skin prior to an injection in order to provide a simple and effective way of reducing pain.

With respect to claim 16, wherein it would be obvious to one of ordinary skill in the art at the time of the invention to utilize sterile ice in order to prevent infection and other medical complications.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin Huh whose telephone number is 571-272-8208. The examiner can normally be reached on M-F: 9:00 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BHH

BHH

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER

Kevin C. Sirmons